Paper No. 20

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte PANKAJ MODI

Appeal No. 2003-1321
Application No. 09/538,829

ON BRIEF

Before WINTERS, GRIMES, and GREEN, Administrative Patent Judges.

GRIMES, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 26, 27, 29, and 37. Claims 28, 30-34, and 36 are also pending; the examiner has indicated that these claims are allowable. The claims on appeal read as follows:

26. A method for administering insulin to the buccal mucosa comprising spraying an effective amount of said insulin to the buccal mucosa using a metered dose inhaler, while resisting substantial inhalation of said insulin.

27. The method of Claim 26, wherein said insulin is in a mixed micelle formulation.

29. The method of Claim 27, wherein said micelles are 1 to 10 nm in size.

37. The method of Claim 26, wherein said insulin is administered in solution.

The examiner relies on the following references:

Radhakrishnan	5,049,389	Sep. 17, 1991
Manning et al. (Manning)	5,770,559	June 23, 1998

Claims 26, 27, and 37 stand rejected under 35 U.S.C. § 102(e) as anticipated by Manning.

Claims 26, 27, 29, and 37 stand rejected under 35 U.S.C. § 103 as obvious in view of either Manning or Radhakrishnan.

We reverse.

Background

Administration of therapeutic polypeptides, such as insulin, is problematic. Polypeptides cannot be administered orally because, among other problems, they are broken down in the digestive tract. Specification, page 1. Thus, insulin is typically administered by injection, which is painful and inconvenient.

Researchers have tried administering therapeutic polypeptides via the buccal mucosa (the cheek lining), but buccal administration presents its own challenges: the mucosal lining is relatively impermeable to large, charged, lipid-insoluble molecules such as polypeptides. Pages 2-3. Thus, polypeptides are administered buccally in combination with "enhancers", substances that facilitate the transport of large molecules across biological membranes. Page 3. These compositions have been formulated as a "localized delivery system using

patches or tablets" and using "large quantities of bile acids and their salts to promote the transport of the large molecules through membranes." Page 4.

The specification discloses an alternative method for buccal delivery of polypeptides: "a system . . . where protein drug was encapsulated in mixed micelles made up of [a] combination of enhancers, e.g. yolk proteins (lecithins)." Page 5. "These mixed micelles are extremely small in size (1 nm to 10 nm), and are smaller than the pores of the membranes in the oral cavity. . . . It is therefore believed that the extremely small size of mixed micelles helps encapsulated molecules penetrate efficiently through the mucosal membranes of the oral cavity." Id.

The disclosed micelle-containing compositions are "[p]referably . . . delivered through metered dose spray devices. Metered does inhalers are known and are a popular pulmonary drug delivery form for some drugs." Page 7. "The present formulation may be absorbed buccally, by ensuring that the person does not inhale the formulation as it is sprayed." Page 8.

Discussion

Claim 26, the only independent claim, is directed to a method for buccal delivery of insulin, comprising spraying the buccal mucosa with an effective amount of insulin using a metered dose inhaler, while the patient "resist[s] substantial inhalation" of the insulin. The examiner rejected most of the claims as anticipated by Manning, and rejected all of the claims as obvious in view of either Manning or Radhakrishnan.

1. Anticipation

The examiner rejected claims 26, 27, and 37 as anticipated by Manning, on the basis that Manning

> discloses pulmonary aerosols comprising insulin micelles that are administered with a metered does inhaler. . . . [Manning] does not specifically state buccal administration of the disclosed compositions, however[,] it is submitted that inhalation of the composition of [Manning] through the mouth would inherently result in buccal administration of the composition.

Examiner's Answer, page 3.

"Under 35 U.S.C. § 102, every limitation of a claim must identically appear in a single prior art reference for it to anticipate the claim." Gechter v. Davidson, 116 F.3d 1454, 1457, 43 USPQ2d 1030, 1032 (Fed. Cir. 1997).

We agree with Appellant that Manning does not anticipate the instant claims. Manning teaches a method of pulmonary drug delivery; i.e., delivery via inhalation. See, e.g., column 8, lines 3-29:

> [T]he size of HIP [hydrophobic ion pair] complexes is controlled by controlling the rates of the mixing of a protein solution. . . . Particles in the 2-10 micron range can be obtained using this procedure. Particles of this size are required to get a sufficient amount of protein delivered to the lung to have a beneficial effect. . . . One example of a protein which could benefit from formation into a fine suspension of HIP complex is DNase, an enzyme currently being used by cystic fibrosis patients to dissolve viscous fluid build up in the lung.

Example 13, cited by the examiner, is also directed to a composition "for pulmonary delivery." Column 21, lines 24-25.

The instantly claimed method, by contrast, is one in which the patient "resist[s] substantial inhalation." As Appellant points out, "a method which

describes delivery of a formulation to the lungs cannot also be a method in which inhalation is resisted. On the contrary, a formulation that delivers a drug to the lungs requires that a patient inhale the formulation." Appeal Brief, page 3.

We do not agree with the examiner that Manning inherently discloses the claimed method. While Manning's method may have resulted in some buccal administration of insulin, that is not what claim 26 is directed to; the claim defines a particular process comprising, among other things, the step of "resisting substantial inhalation." This limitation is not inherently disclosed by the prior art; as discussed above, the method of administration disclosed by Manning requires inhalation.

Since Manning does not teach every limitation of the claimed method, it does not anticipate. The rejection under 35 U.S.C. § 102(e) is reversed.

2. Obviousness

The examiner also rejected all of the claims as obvious in view of either Manning or Radhakrishnan. The examiner relied on the same reasoning put forward to support the anticipation rejection: the references teach administration of insulin-containing micelles via a metered dose inhaler; although the references do not state that the composition is administered buccally, the examiner "submitted that inhalation of the composition of [the references] through the mouth would inherently result in buccal administration of the composition." See the Examiner's Answer, pages 4-5 and 6.

We agree with Appellants that the examiner has not shown that the cited references would have made obvious the process of the present claims. Prima

facie obviousness requires, among other things, showing that all the limitations of the claimed invention would have been obvious to those of ordinary skill in the art. See, e.g., In re Lowry, 32 F.3d 1579, 1582, 32 USPQ2d 1031, 1034 (Fed. Cir. 1994) ("The Patent and Trademark Office (PTO) must consider all claim limitations when determining patentability of an invention over the prior art."); In re Ochiai, 71 F.3d 1565, 1572, 37 USPQ2d 1127, 1133 (Fed. Cir. 1995) (proper § 103 analysis requires "a searching comparison of the claimed invention – including all its limitations – with the teaching of the prior art.").

As discussed above, the references do not teach "resisting substantial inhalation" of the composition from the metered dose inhaler. Nor has the examiner attempted to explain why such a step would have been obvious to those skilled in the art. Rather, the examiner relies on the same "inherency" argument that he made with respect to anticipation. For the reasons discussed, above, we do not agree that the references inherently disclose a method comprising "resisting substantial inhalation."

Nor do we find that the references would have made such a step obvious to those skilled in the art. In fact, as Appellant argues, the references seem to teach away from such a step: since the method disclosed in the references requires inhalation of the therapeutic composition, those skilled in the art would have been led away from a method comprising "resisting substantial inhalation."

Neither Manning nor Radhakrishnan support a prima facie case of obviousness. The rejection under 35 U.S.C. § 103 is reversed.

Other Issues

Earlier in prosecution, all of the pending claims were rejected for obviousness-type double patenting over the claims of application 09/386,285, now U.S. Patent 6,221,378. Appellant overcame the rejection by filing a terminal disclaimer (Paper No. 11, filed Nov. 13, 2001).

In the time since this appeal was briefed, Appellant has been issued U.S. Patent 6,432,383. The '383 patent's claim 1 reads as follows:

> 1. A method for administering insulin to the buccal mucosa comprising spraying an effective amount of said insulin to the buccal mucosa, using a metered dose inhaler.

Thus, claim 1 of the '383 patent appears to be generic to instant claim 1. Upon return of this case, the examiner should consider whether, in the absence of a terminal disclaimer referencing the '383 patent, any of the claims pending in the instant application are unpatentable for obviousness-type double patenting. If so, a rejection on that basis would be appropriate.

Summary

The cited references do not disclose or suggest the instantly claimed process. We therefore reverse the rejections under 35 U.S.C. §§ 102(e) and 103.

REVERSED

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